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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,231	02/24/2004	Mark Gelfand	4491-2	1587
32488	7590	11/26/2008		
Iandiorio Teska & Coleman 260 Bear Hill Road Waltham, MA 02451			EXAMINER MATTHEWS, WILLIAM H	
			ART UNIT 3774	PAPER NUMBER
			MAIL DATE 11/26/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/784,231	GELFAND ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	William H. Matthews (Howie)	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11 August 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,3-14 and 16-46 is/are pending in the application.

4a) Of the above claim(s) 28-46 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,3-14,16-27 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-27 have been considered but are not persuasive. With regard to Doty et al. and Sterman et al., Applicant argues the cited references fail to suggest the claimed purpose of the present claims. This is not persuasive because a reference anticipates the method if each claimed step is provided in the reference. The fact that Doty and Sterman et al. did not appreciate additional benefits of their methods does not render a method of doing the same steps for a different purpose novel.

With further regard to Sterman, Applicant states the amendment to change "at least partially occlude" to "partially occlude" overcomes Sterman because he discloses complete occlusion. This is not persuasive because before, or during, balloon expansion a state of partial occlusion exists. Furthermore, the claims recite the open-ended transitional phrase "comprising". Thus the claims are readable on a method including complete occlusion. See MPEP 2111.03.

Regarding the 112 2<sup>nd</sup> paragraph rejection based on "high concentration", Applicant has not shown anywhere in the specification placing a numerical value or range to define "high concentration". Examiner maintains the rejection because the scope of "high concentration" is not defined by the specification with any specificity, rather only based on relativity based on time.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,10,14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 10, 14, and 15 recite “high concentration”. The specification does not reasonably apprise one of ordinary skill in the art as to the meaning of “high”. See MPEP 2173.05(b). For purposes of examination, high concentration is not given patentable weight as to a required level of concentration.

Claim 14 is further indefinite because it is unclear if the steps of increasing pressure and injecting contrast are positively recited because the step of injecting contrast isn’t recited until dependent claim 23. Therefore the claim appears to be a use claim which doesn’t necessarily perform any steps.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,3-5,8-12,14,16-19,22,25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Doty et al. Effect of Increased Renal Venous Pressure on Renal Function (“Doty”).

Doty discloses a method including the steps of increasing renal venous pressure by 30 mmHg above baseline including the substeps of injecting contrast (inulin) and inserting a catheter into a renal vein wherein renal functions are reduced as a result thereof.

Claims 1,3-6,8,9,10,14-20,22,24 are rejected under 35 U.S.C. 102(e) as being anticipated by Sterman et al. USPN 6699231 (“Sterman”).

Sterman disclose a method of protecting a kidney from an insult by reducing renal functions of the kidney due to increasing pressure in the renal vein (see col. 22 line 62 - col. 23 line 13, col. 24 line 63 – col. 25 line 16, col. 25 line 63 – col. 26 line 17). The method further comprises monitoring/adjusting pressure (col. 15 line 31- col. 16 line 10) and insertion of a balloon catheter to at least partially occlude the renal vein. Regarding claims 10 and 24, Sterman discloses injection of contrast media (col. 4 lines 59- col. 5 line 1, col. 25 line 63- col. 26 line 17), the procedure may last up to four hours or longer (col. 5 lines 19-32), and the procedure could entail delivery and uptake of contrast agents in another region of the body while the renal vein is occluded.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7,13,21,27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sterman et al. USPN 6699231 (“Sterman”).

Sterman is described *supra*. Sterman teaches monitoring the pressure and adjusting the pressure by altering fluid volume during recirculation (col. 15 line 31- col. 16 line 10) and further a pressure control means (col. 15 lines 21-30), but fail to describe a step of increasing pressure by adjusting the balloon. However it would have been obvious to one of ordinary skill in the art to include the step of adjusting the balloon to adjust pressure because it is well known that pressure could be reduced, in the event of overpressurization, by deflating the occluding balloon. On the other hand, should the pressure drop, due to a leak about the occluding balloon, it would have been obvious to a skilled artisan to increase balloon pressure to fully occlude the vessel as desired by Sterman.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/  
Primary Examiner  
Art Unit 3774